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APPLICATION NO	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 603,866	06 26 2000	Avi J. Ashkenazi	P1761R1	2405

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Genentech Inc
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South San Francisco, CA 94080

EXAMINER

KAUFMAN, CLAIRE M

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 03 11 2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/603,866

Applicant(s)

ASHKENAZI ET AL.

Examiner

Claire M. Kaufman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 49-54 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 49-54 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other:

DETAILED ACTION

The amendments filed 10/22/02 and 11/20/02 have been entered.

Drawings

The receipt of formal drawings is acknowledged.

Response to Arguments

The rejection of claim 1 and 7 and dependent claims under 35 USC 112, second paragraph, is withdrawn in view of the amendment to the claims.

The rejection of claims 1, 5-11 and 49-54 under 35 USC 112, first paragraph, is withdrawn in part. The rejection no longer encompasses scope of enablement for the Apo-2 ligand because of the amendment to the claims and in view of Applicants' arguments (note especially the discussion of Table I (see also page 44) of the specification supporting parts (a)-(d) of the amendments to claims 1 and 49). The claims, however, with the exception of claims 50 and 51 remain rejected for the scope of enablement of divalent metal ions.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claim 1, 5-11, 49 and 52-54 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a formulation as set forth in claims 1 and 49 wherein the divalent metal ions comprise zinc or cobalt, does not reasonably provide enablement for other divalent metal ions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use and/or make the invention commensurate in scope with these claims for the reasons set forth in the previous Office action, paper #15, pages 3-4.

Applicants argue the specification need not provide a working example of each and every divalent metal ion contemplated and that there is sufficient description for the skilled artisan to make and used the claimed formulations of Apo-2 ligand without undue experimentation. The

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argument has been fully considered, but is not persuasive. While a working example of each contemplated ion is not required, it is maintained that there is not sufficient description or guidance in the specification combined with the low skill level in the art for this subject matter and wide breadth of the claims to allow the skilled artisan to make and/or use the formulation with a divalent metal ion other than zinc or cobalt. As stated in the previously Office action in the middle of page 4 of the specification it is said, "However, the other divalent ions tested, Cd, Ni, Cu, do not bind to Apo-2L..." (see TABLE II of the specification on page 48). Not only is there a lack of examples or guidance for making and using the formulation with a metal ion other than Zn or Co, but the specification teaches away from it. It is maintained that it would require undue experimentation to practice the claimed invention commensurate with its current scope.

Claim Rejections - 35 USC § 102

Claims 1-11 and 49-53 remain rejected under 35 U.S.C. 102(b) as being anticipated by Wiley (Immunity, 1995) for the reasons set forth in the previous Office action on page 5.

Applicants argue it is improper to read into the contents of the sodium citrate for the presence of zinc. The argument has been fully considered, but is not persuasive. First, Fisher Chemicals is a large and widely used chemical source company, so that it would be expected that their sodium citrate composition is representative of those generally available and used. Second, Wiley also used Tris, pH 8, which was used to neutralize the sodium citrate (p. 680, second full paragraph). Tris also appears to be what Applicants used (p. 48, line 13) to reconstitute the purified Apo-2L and what was the contributor of metals, including zinc, shown in TABLE II. Therefore, it appears more likely than not that the formulation of Wiley did provide divalent metal ions as required by the instant claims.

Applicants argue that the lack of information in Wiley about the molar ratio leaves a critical gap. The argument has been fully considered, but is not persuasive. Because the molar ratio required by the claims is simply the range of "<2X", and because the metals are only present in trace amounts, one would reasonably expect that the formulation of Wiley et al would meet the required molar ration recited in the claims.

Applicants argue that Example 5 of the specification provides an analysis of buffer used in Apo-2L preparation and does not suggest that zinc and cobalt are inherent in an Apo-2L

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formulation. The argument has been fully considered, but is not persuasive. Because Applicants specifically say they did not add additional metals and relied only on buffer contaminants, it is more likely than not that the same divalent metal contaminants were present in the buffers of Wiley. Therefore, it does appear, absent evidence to the contrary, that the metal ions would be inherent in buffers used by Wiley.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Claire M. Kaufman, whose telephone number is (703) 305-5791. Dr. Kaufman can generally be reached Monday through Thursday from 8:30AM to 12:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (703) 308-6564.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Official papers filed by fax should be directed to (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294. **NOTE:** If applicant *does* submit a paper by fax, the original signed copy should be retained by the applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED**

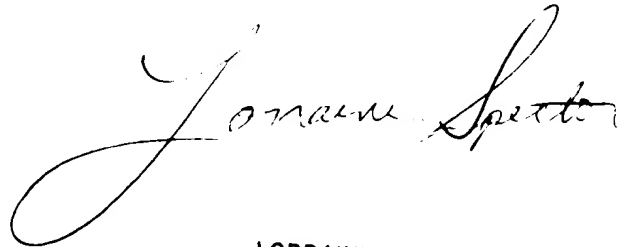
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so as to avoid the processing of duplicate papers in the Office. **Please** advise the examiner at the telephone number above before facsimile transmission.

Claire M. Kaufman, Ph.D.


Patent Examiner, Art Unit 1646

March 10, 2003



LORRAINE SPECTOR
PRIMARY EXAMINER